510(k) - Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

1. Device Name and Classification

Product Name:	*syngo.CT Dynamic Angio*
Classification Name:	Accessory to Computed Tomography System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90 JAK

2. Importer/Distributor Establishment:

Registration Number: 2240869

Siemens Medical Solutions, Inc.
51 Valley Stream Pkwy
Malvern, PA 19355

3. Manufacturing Facility:

Siemens AG
Medical Solutions
Henkestrasse 127

D-91052 Erlangen, Germany

4. Contact Person:

Mr. Ralf Hofmann
Regulatory Affairs Specialist
Siemensstr.1; D-91301 Forchheim
Phone: +49 9191 18-8170
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5. Date of Preparation of Summary: January 13, 2012

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

6. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

7. Device Description and Intended Use:

syngo.CT Dynamic Angio is a software, which was developed to visualize dynamic CT datasets in a three and four dimensional view. Possible input data are Siemens CT Dynamic Sequence, Dynamic Multiscan, Adaptive 4D Spiral and Heart Perfusion Scanning datasets.

syngo.CT Dynamic Angio supports the overlay free visualization of the vessel enhancement with the help of motion correction and bone segmentation. The software can be used to run a movie of a time series or to create CT phase volumes (e.g. arterial phase or venous phase) by combining multiple neighboring time points from the dynamic CT data. It also supports the evaluation of regions of interest and the visual inspection of time attenuation curves.

Indication for Use:
The *syngo*.CT Dynamic Angio software package has been designed to evaluate CT data which has been continuously acquired with computed tomography (CT) imaging systems. Contrast enhanced CT images are used to visualize the flow of contrast from the arteries to the veins.
syngo.CT Dynamic Angio can be used to assist the physician in the diagnosis of blood vessels and it supports in the evaluation of regions of interest, the visual inspection of time attenuation curves, and the creation of specific CT volumes, for example, arterial or venous phase. It will aid in the inspection of diseases which affect the vessel system, for example, vessel stenosis, collateral or late filling of vessels, vascular malformations, control of stent graft extravasation, or in the evaluation of tumor vascularization.

8. Substantial Equivalence:

syngo.CT Dynamic Angio software package, designed for post processing images that have been continuously acquired with computed tomography (CT) imaging systems which meet certain minimal requirements, is substantially equivalent to the following devices:

Manufacturer	Product	510(k)	Clearance date
1. Siemens AG	syngo® Inspace 4D	K062673	22/09/2006
2. Siemens AG	syngo® Volume Perfusion CT- Body	K092013	17/07/2009
3. Siemens AG	syngo® Volume Perfusion CT- Neuro	K073238	03/01/2008

9. Summary of Technological Characteristics of the Principle Device as Compared with the Predicate Devices

*syngo.CT Dynamic Angio*is a post-processing software package which provides a combination of functionality similar to functionality provided by one or more of the predicate devices as listed above. It uses the same data for evaluation as the predicate devices and provides results in the same format as the predicate devices

All result volumes created by CT Dynamic Angio are stored in separate series and consist of a set of standard DICOM single frame CT images. All finding snapshot images are stored in a different series as DICOM secondary captures.

As basis for data viewing, *syngo.CT Dynamic Angio* uses basic reader and image display functionality as provided by syngo.via. Different visualization filters like multiplanar reformatting (MPR, MPR Thick), maximum intensity projection (MIP, MIP Thin) and volume rendering techniques (VRT, VRT Thin) can be applied. Windowing of the visualized data can be done by mouse interaction and with predefined CT window presets. Zooming and panning of the CT volumes is supported.

In addition to basic viewing capabilities, *syngo.CT Dynamic Angio* provides tools for visualization, analysis and reporting of vascular conditions.

Standard syngo.via analysis tools are Distance Line, Pixel Lens, Marker, Arrow and ROI (Region of Interest).

Accordingly, *syngo.CT Dynamic Angio* has equivalent technological characteristics as the predicate devices. Moreover, *syngo.CT Dynamic Angio* uses image processing algorithms, in order to provide results that are substantially equivalent to those obtained with one or more of the predicate devices.

Siemens is of the opinion that the *syngo.CT Dynamic Angio* software package is intended for the same indications for use as the predicate devices. It does not introduce any new potential safety risk and is substantially equivalent to and performs as well as the predicate devices.

10. Summary of non-clinical and/or clinical testing

*syngo.CT Dynamic Angio*is designed to fullfill the requirements of following standards

- IEC 60601-1-6 : 2006; Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
- IEC 62304 : 2006, "Medical Device Software – Software Lifecycle Processes"
- ISO 14971:2007; Medical devices - Application of risk management to medical devices
- DICOM (Digital Imaging and Communications in Medicine) Standard: 2008
  DICOM conformity is fully covered by syngo.via implementations.

Non clinical tests are conducted for *syngo.CT Dynamic Angio* software package during product development. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Siemens AG Medical Solutions
% Mr. Hubert Stuiber
Responsible Third Party Official
TÜV SÜD America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

APR 13 2012

Re: K120331
Trade/Device Name: syngo.CT Dynamic Angio
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 21, 2012
Received: March 23, 2012

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for use

510(k) Number (if known): _____

Device Name: **syngo.CT Dynamic Angio**

The *syngo*.CT Dynamic Angio software package has been designed to evaluate CT data which has been continuously acquired with computed tomography (CT) imaging systems. Contrast enhanced CT images are used to visualize the flow of contrast from the arteries to the veins.
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Prescription Use	X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)			(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K120331